

PACIFIC | CLINICAL | RESEARCH | GROUP



AUSTRALIA | NEW ZEALAND



Dependable People : Reliable Outcomes



Dr. Ross Prpic, MBBS, FRACP

Sydney-based Dr. Prpic is the Chairman of Pacific Clinical Research Group (PCRG) Australasia, a highly selective and successful Contract Research Organization.

Dr. Prpic is a fully certified Interventional Cardiologist and has long been actively involved in international, Australian and New Zealand clinical research programs. This involvement encompasses operational experience in clinical trials in a wide range of therapeutic areas.

After completing his medical degree at The University of Melbourne in 1989, Dr. Prpic worked at a number of prestigious Australian hospitals and achieved Fellowship of the Royal Australasian College of Physicians (Cardiology) in 1996. In 1998 he was recruited to the United States and was made Associate Director, Angiographic Core Laboratory at Brigham & Women's Hospital, Boston. In that role he was either the senior or principal Angiographic Investigator for some 45 clinical trials.

Subsequently, Harvard Clinical Research Institute appointed Dr. Prpic as Medical Director, Trial Design and Development, where he was involved in more than 50 clinical trials of new vascular devices and cardiac therapies.

Since returning to Australia and founding PCRG in 2003, he has spearheaded the company's clinical trial and regulatory compliance undertakings and grown the company into a



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highly respected and reliable provider of quality clinical trial programs.

Dr. Prpic continues to act as a Specialist Adviser to numerous medical device and pharmaceutical companies in the United States, Europe and Asia, and to a number of US financial companies. In addition, he serves on international editorial boards as an Ad hoc Reviewer and is an invited lecturer at major international scientific conferences. He has also written multiple journal articles, reviews and textbook chapters.

Pacific Clinical Research Group

PCRG has its headquarters in Sydney, Australia. The company is a highly selective and successful Contract Research Organization (CRO) servicing sponsors who wish to conduct trials in Australia and New Zealand.

The company offers a tailored approach to clinical trial execution and costing, and thrives on helping its clients bring products and services to market.

Based on its founder's area of specialty, PCRG initially focused on early stage trials of medical devices and drugs to address cardiovascular disease. By the end of 2008 however, the company was working in many therapeutic arenas and had successfully completed more than 50 pharmaceutical and device trials. These ranged from small early-phase programs to multi-site studies across many countries.

The company's success to-date has enhanced its international reputation and enabled it to attract professionals of the highest caliber. PCRG has expanded its team, with the expertise and capacity to undertake complex clinical trials of pharmaceuticals, devices, biotechnology solutions and diagnostics in all therapeutic areas.

With its in-depth understanding of the Australian and New Zealand healthcare and regulatory environment, and through its relationships with key personal contacts at all levels, PCRG has become one of the most respected CROs in the Southern Hemisphere.

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Helping clients bring products and services to market.



The PCRG Advantage

One of PCRG's most formidable advantages is the quality, experience and dedication of its staff.

The second is the comprehensive scope and thoroughness of the company's tried and tested business practices.

And the third is PCRG's extensive network of contacts throughout the healthcare fraternity both in Australia, New Zealand and across the globe.

PCRG People

Everyone of PCRG's clinical team holds a university degree in life sciences or has healthcare qualifications. Staff have previously worked in medical research not only in Australia and New Zealand, but also the United States, Europe and Asia.

In a profession where employment turnover rates are traditionally high, PCRG staff members are,

by contrast, exceptionally long-serving. This pattern of lengthy tenure is thanks to ongoing training, individual mentoring, direct exposure to leading clinicians and a company culture which emphasizes job satisfaction in relationships with co-workers, sponsors and trial site personnel.

PCRG Business Practices

The company treats every clinical trial as unique. Trials are designed to accommodate sponsors' specific needs and are staffed with clinical and management team structures for optimum time- and cost-effectiveness, defined points of contact and reporting disciplines.

The company maintains complete and up-to-date Standard Operating Procedures applicable to appropriate international quality standards. Similarly, PCRG maintains current compliance procedures for all Australian and New Zealand regulatory jurisdictions.





‘The company’s core expertise lies in the full cycle conduct of pharmaceutical and medical device trials...’

PCRG Networks

The company has affiliates throughout the Asia Pacific region and strategic partners at medical centers of excellence in the United States. PCRG’s ready access to world renowned Key Opinion Leaders adds significant value to the company’s offering. Partners are consulted on and assist in novel pre-clinical planning and bio-statistical and regulatory strategy development.

PCRG Services

Pacific Clinical Research Group is a full service CRO. The company’s core expertise lies in the full cycle conduct of pharmaceutical and medical device trials in Australia and New Zealand. In addition, PCRG has a wealth of experience and a niche interest in early phase device and drug development.

PCRG services include but are not limited to -

- Early-phase strategic planning
- Assessment of pre-clinical programs
- Introduction to Key Opinion Leaders
- Identification of appropriate clinical trial sites
- Trial design and development
- Preparation of Ethics Committee submission packages
- Assistance with regulatory submissions
- Organization of Investigators’ Meetings
- Overall project management
- Site management and quality assurance
- Bio-statistical support
- Data management
- Medical report writing
- Clinical events adjudication
- Medical management and monitoring
- Data and safety monitoring board coordination
- Assistance with the import of investigational drugs and devices
- Compliance with local legislative requirements

Tried and tested business practices



PCRG Substance

While each of the services listed on the previous page conforms to high ethical standards in accordance with ICH-GCP and standard operating procedures, PCRG prides itself on flexibility with services structured to precisely match sponsors' requirements in terms of timescale, cost and reporting.

Early-phase strategic planning

PCRG's Chairman leads the strategy planning process, together with the appointed Project Leader. Planning includes review of pre-clinical data, recommendations regarding trial design and identification of suitable clinical sites which have the proven ability to conduct the specific trial. Where required, PCRG will also conduct a formal evaluation of sites.

Thought leadership

Through PCRG's collaboration with world renowned clinician-researchers, research sponsors and clinical sites, the company delivers the expertise and infrastructure to demonstrate the safety and efficacy of new devices and pharmacological agents.

Trial resourcing

PCRG trial teams are assembled to ensure the optimum resource for specific study needs and geographies. PCRG Project Leaders are the sponsors' primary points of contact. PCRG Project Leaders report directly to the Chairman and liaise with any third parties involved.

Documentation

PCRG generates all necessary trial documentation including but not limited to the Investigational Plan, Patient Information Sheet, Informed Consent Document, Investigator Brochure and Case Report Forms. In every case, documentation is specific to the sites involved in the trial, regulatory demands and the sponsors' particular requirements.

Data management

PCRG undertakes extensive follow up with clinical sites on behalf of sponsors' data managers over the entire clinical trial period. This ranges from the development of the Data Management Plan, the database itself, to the delivery of a clean data file upon completion of the study. PCRG tracks, enters, verifies and cleans the provided data. PCRG generates data queries, liaises with sites to resolve them and conducts database quality audits.

Compliance

A key benefit for clients is PCRG's ability to take on the regulatory compliance workload. This is particularly important for sponsors with no previous experience of clinical trials in the Asia Pacific region.

Site management

In addition to being personally involved in the identification of appropriate clinical trial sites, PCRG Management oversees the provision of extensive local support during the Ethics Committee submission stage. PCRG provides full

PCRG takes on the regulatory compliance workload

on-site support including monitoring services, and participates in the training of monitors, clinical site research staff and organization of Investigators' Meetings.

Medical management

PCRG provides appropriately qualified medical specialists to deal with any Serious Adverse Events and Adverse Events that may occur during the conduct of a trial. PCRG maintains study databases in order to track such events, and

reports them in accordance with the requirements of the local regulatory authorities. Where required, PCRG assembles Clinical Events Committees and/or Data Safety Monitoring Boards to ensure appropriate independent trial oversight.

In everything, PCRG's attention to detail, its determination to exceed clients' expectations, its very considerable experience in the field and the quality of its people offers sponsors exceptional service and peace-of-mind.

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Exceptional service and peace of mind

A horizontal banner with a light blue background. On the left side, there is a close-up image of a silver stethoscope. A white ECG (heart rate) line runs across the banner, starting from the left and ending on the right. The text is centered over the ECG line.

Pacific Clinical Research Group Pty. Ltd.
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